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ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FIRST NAMED INVENTOR FILING DATE 19634YDACA 10/767,521 5530 01/29/2004 Bruce L. Daugherty **EXAMINER** 210 02/01/2006 7590 MERCK AND CO., INC MERTZ, PREMA MARIA P O BOX 2000 **ART UNIT** PAPER NUMBER RAHWAY, NJ 07065-0907 1646

DATE MAILED: 02/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary		Application	1 No.	Applicant(s)	
		10/767,521		DAUGHERTY ET AL.	
		Examiner		Art Unit	
		Prema M. N	/lertz	1646	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1)🖾	Responsive to communication(s) filed on 28 November 2005.				
2a)□	This action is FINAL. 2b)⊠ This action is non-final.				
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
5)□ 6)⊠ 7)□	 4) ☐ Claim(s) 36-49 is/are pending in the application. 4a) Of the above claim(s) 43-49 is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 36-42 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement. 				
Application Papers					
9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
2) Notice	t(s) se of References Cited (PTO-892) se of Draftsperson's Patent Drawing Review (PTO-948) smation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) str No(s)/Mail Date 5/10/2004.		4) Interview Summary (Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:	•	

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 36-42) in the reply filed on 11/28/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 43-49 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

2. The disclosure is objected to because of the following informalities:

On page 22, lines 6-8, the old address of ATCC in Rockville, MD is disclosed. The new address is ATCC, 10801 University Boulevard, Manassas, VA 20110-2209.

Appropriate correction in the specification is required.

Claim Rejections - 35 USC § 112, first paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 42 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The cell line recited in claim 48 is essential to the claimed invention. The cell line AML14.3D10, disclosed on page 22, lines 6-8, of the specification, must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The instant specification does not disclose a repeatable process to obtain the cell line, and it is not apparent if this cell line is readily available to the public. If the deposit has been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the cell line has been deposited under the Budapest Treaty and that the cell line will be irrevocably and without restriction or condition be released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample or for the enforceable life of the patent whichever is longer. See 37 CFR 1.806. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the cell line described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the

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depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Claim Rejections - 35 USC § 112, second paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36, line 2, is rejected as vague and indefinite because it recites "having" rather than the conventional "comprising". It is suggested that the claim be amended to recite "comprising".

Claim 36, line 2, is improper because it recites "receptor receptor". Appropriate correction is requested.

Claim 39, line 2, is improper because it recites "receptor receptor". Appropriate correction is requested.

Claims 37-38, 40-42 are rejected as vague and indefinite insofar as they depend on the above rejected claims for their limitations.

Claim Rejections - 35 USC § 102

5a. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 36, 39-41 are rejected under 35 U.S.C. 102(a) as being anticipated by Combadiere et al. (1995).

Combadiere et al. teach the cloning of a cDNA encoding a human CC chemokine receptor 3 (CC CKR3) and expression of the recombinant receptor in HEK 293 cells (which do not naturally express the human CC chemokine receptor 3), the CKR3 receptor belonging to the G protein-coupled family of receptors (see page 16491, abstract lines 1-13 and column 2, third paragraph; page 16492, Figure 1). A copy of the comparison of SEQ ID NO:1 of the instant invention and the amino acid sequence of the receptor disclosed in the reference is enclosed at the end of this action (SEQUENCE COMPARISON "A") which depicts 100% sequence identity between the amino acid sequences of the receptor protein. Therefore, a recombinant human eosinophil eotaxin receptor having the amino acid sequence of SEQ ID NO:1 and encoded by a nucleic acid as set forth in SEQ ID NO:2 as disclosed by Combadiere et al anticipates instant claims 36, 39-41.

5b. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

⁽e) the invention was described in-

⁽¹⁾ an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

⁽²⁾ a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

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Claims 36, 38-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Gray et al. (US Patent No. 6.265,184).

Gray et al. teach the cloning of a cDNA encoding a chemokine receptor 88-2B and expression of the recombinant receptor in HEK 293 cells (which do not naturally express the 88-2B receptor), the 88-2B receptor belonging to the G protein-coupled family of receptors (see column 2, lines 17-31). A comparison of nucleotide sequence SEQ ID NO:2 of the instant invention and nucleotide sequence SEQ ID NO:3 of the 88-2B receptor disclosed in the reference depicts 100% sequence identity between the two nucleotide sequences. The reference also discloses that the cDNA encoding the 88-2B receptor was cloned into a eukaryotic expression vector, pRc/CMV, which contains a promoter operably linked to the cDNA insert encoding the receptor, as shown by the ability of the vector to be expressing a functional receptor (column 11, lines 56-67; column 12, lines 1-20). Host cells were transformed with the cDNA in the vector (column 12, lines 9-19). Therefore, the cDNA sequence disclosed in the Gray et al. reference meets the limitations of a nucleic acid molecule of nucleotide sequence set forth in SEQ ID NO:2.

Claim rejections-35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all 6. obviousness rejections set forth in this Office action:
- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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6a. Claims 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Combadiere et al. (1995).

The teachings of Combadiere et al. have been set forth above in paragraph 5a above. However, Combadiere et al. does not teach the 5' genomic DNA flanking sequence encoding the human eosinophil eotaxin receptor or the terminator region of the cDNA encoding the human eosinophil eotaxin receptor.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the instant invention was made to use as a probe the cDNA encoding the human eosinophil eotaxin receptor as disclosed by Combadiere to obtain the 5' genomic DNA flanking sequence as set forth in SEQ ID NO:3 or the terminator region of the cDNA encoding the human eosinophil eotaxin receptor as set forth in SEQ ID NO:4, to determine and study the location and structure of the regulatory regions that control expression of the human eosinophil eotaxin receptor gene. Obtaining the 5' genomic DNA flanking sequence encoding the human eosinophil eotaxin receptor or the terminator region of the cDNA encoding the human eosinophil eotaxin receptor region by employing those methods that were old and well known in the art of molecular biology at the time that the instant invention was made would have been *prima facie* obvious to an artisan in light of the Combadiere et al publication.

6b. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al. (US Patent No. 6.265,184).

The teachings of Gray et al. have been set forth above in paragraph 5b above. However, Gray does not teach the 5' genomic DNA flanking sequence encoding the human eosinophil eotaxin receptor.

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It would have been *prima facie* obvious to one of ordinary skill in the art at the time the instant invention was made to use as a probe the cDNA encoding the human eosinophil eotaxin receptor disclosed by the Gray reference to obtain the 5' genomic DNA flanking sequence as set forth in SEQ ID NO:3 to determine and study the location and structure of the regulatory regions that control expression of the human eosinophil eotaxin receptor gene. Obtaining the 5' genomic DNA flanking sequence encoding the human eosinophil eotaxin receptor by employing those methods that were old and well known in the art of molecular biology at the time that the instant invention was made would have been *prima facie* obvious to an artisan in light of the Gray et al publication.

Conclusion

No claim is allowed.

Claims 36-42 are rejected.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz Ph.D., J.D.

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Primary Examiner Art Unit 1646 January 18, 2006